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Mazdoor Kisan Shakti Sangathan
"The Right to Information, The Right to Live"

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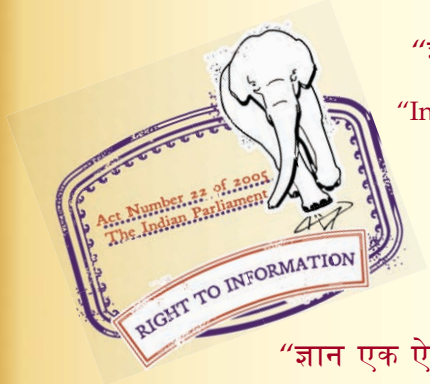
"Step Out From the Old to the New"

IS 11088 (1984): Guide for retrieval and analysis of metallic orthopaedic implants [MHD 2: Orthopaedic Instruments, Implants and Accessories]



"ज्ञान से एक नये भारत का निर्माण"
Satyanarayan Gangaram Pitroda
"Invent a New India Using Knowledge"

"ज्ञान एक ऐसा खजाना है जो कभी चुराया नहीं जा सकता है"
Bhartṛhari—Nītiśatakam
"Knowledge is such a treasure which cannot be stolen"

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(Reaffirmed 2002)

Indian Standard

GUIDE FOR RETRIEVAL AND ANALYSIS OF METALLIC ORTHOPAEDIC IMPLANTS

Orthopaedic Instruments & Accessories Sectional Committee, CPDC 24; Implants and Accessories Subcommittee, CPDC 24 : 1 [Ref : Doc: CPDC 24(1734)]

1. Scope — This guide covers the protocol for the retrieval and analysis of metallic orthopaedic implants used in human patients. It applies to all implants removed from the patient for the purpose of clinical and implant performance evaluation.

2. Summary of the Guide — This guide covers the clinical data to be recorded and the material characterizations to be performed when an implant is retrieved. The clinical data include a case history review, roentgenogram review, tissue culture, and histological evaluation of tissue. The meterial characterizations include chemical composition, macroscopic and microscopic examination and mechanical property determinations. A photographic documentation of findings shall be made in accordance with the requirements of this guide.

3. Significance — This is a test protocol for standardizing the retrieval and analysis of orthopaedic metallic implants. The results obtained by several independent investigators using this protocol can be correlated in order to relate the performance with materials characteristics. Performance criteria can be established and information useful for updating material and device standards can be generated.

4. Implant Retrieval

4.1 *Photographic Record* — If possible, make a photographic record of the implant in place prior to its removal. Also, immediately after its removal, make a photographic record of the implant and surgical site.

4.2 *Microbiological Culture* — Obtain a swab prior to implant removal.

4.3 *Tissue Sample* — Prior to implant removal or immediately thereafter, obtain tissue samples from a location adjacent to the implant and, if possible, extending into normal tissue. Record the location of the site of tissue removal relative to the implant.

4.4 *Orientation of Components* — Clearly identify all components as to surgical placement so that they may be maintained in the same relative position to one another.

4.5 *Implant Sterilization* — As a precautionary measure, all removed implants should be sterilized by an appropriate means.

5. Case History Review

5.1 *Standard Form* — A standard form indicating the information to be recorded about each case is given in Appendix A. Only those items requiring explanatory notes are discussed in **5.1.1** to **5.1.3**.

5.1.1 *Functional level of patient attained between insertion and removal* — The criteria are for lower limb implants only. If the report is for other than a lower limb implant, a similar analysis should be made and recorded.

5.1.2 *Examination of tissue*

5.1.2.1 Record the gross characteristics of the tissue immediately adjacent to the implant as to consistency and colour, as seen by the naked eye, and with a hand lens or dissecting microscope. Process the excised tissue for histopathological and for such other studies as are appropriate; elective histological, chemical, mechanical, radiological, etc. Cut the sample into appropriate fractions for such studies. Use standard laboratory practice for the histological preparation of the tissue with regard to the trimming of tissue blocks, fixation, washing, embedding, and staining. Report the methodology.

5.1.2.2 *Histopathological observations* — Classify the amount of tissue reaction in regard to the thickness of the scar, the presence of leucocytes or other tissue cells, the presence of particles detectable by polarized light, and such other indications of interaction of tissue and material as might be observed. Note evidence of neoplasia or tissue degeneration. Attach a copy of the histopathological report.

Adopted 22 November 1984

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5.1.3 *Roentgenogram review* — Review all pertinent roentgenograms. Attach a copy of the summary and the original radiographic reports, if available. Obtain a reduced photographic copy of any roentgenogram that is judged essential to support the conclusion (*see* Appendix A).

6. Analysis of Implant

6.1 Perform a separate analysis for each component of a device, if possible.

6.2 *Fractographic Examination (If Implant is Fractured)* — Analyze the fracture surface by suitable techniques to ascert in the mode of fracture. In no event should the fracture surface be destructively evaluated. If the device has mechanically failed, it is important to remember that it may be classified as legal evidence.

6.3 *Standard Form* — A standard form indicating the information to be recorded about each case is given in Appendix B. Only those items requiring explanatory notes are discussed in **6.3.1** through **6.3.4**.

6.3.1 *Macroscopic examination* — Perform this examination at magnifications up to 70 X with the aid of a stereomicroscope. Record an estimate as to the degree of findings in accordance with Appendix B.

6.3.2 *Microscopical examination*

6.3.2.1 Use standard metallographic preparation and techniques suitable for the material under investigation.

6.3.2.2 Determine the inclusion content in accordance with the relevant Indian Standard.

6.3.2.3 Determine the grain size in accordance with the relevant Indian Standard.

6.3.3 *Type of material* — Determine the chemical composition. In the event that the composition does not meet the requirements of relevant Indian Standard, then use the applicable referee analysis procedure.

6.3.4 *Mechanical properties of implant material* — Determine the hardness and the tensile properties in accordance with the relevant Indian Standards.

APPENDIX A

(*Clauses* 5.1 *and* 5.1.3)

RECOVERY OF IMPLANTS, CASE HISTORY REVIEW

A-1. Date inserted.....

A-2. Date removed.....

A-3. Implant, type.....

A-4. Patient's sex .....

A-5. Patient's date of birth.....

A-6. Patient's weight .....

A-7. Implant location.....

A-8. Patient's activity or occupation.....

A-9. History of foreign body sensitivity.....

A-10. a) Diagnosis at insertion .....

b) Trauma simple or comminuted; open or closed .....

c) Contributory conditions (for example, alcoholism, senility) .....

A-11. Operation at insertion .....

A-12. Antibiotics at insertion, if yes, answer the following:

a) Reasons for antibiotics:

i)
ii)
iii)

b) Type
c) Dosage
d) Duration

A-13. Functional level of the patient attained between insertion and removal (ambulatory, ambulatory with aids, nonambulatory). Comment on any unusual physical activity or event for this treatment.

A-14. Roentgenogram review (Indicate *Yes*, *No*, *Doubt*, or *Not applicable*)

a) Bony change in relation to implant
b) Absorption or rarefaction
c) Increased density (sclerosis-compaction)
d) Non-union
e) Bone fragments held apart
f) Migration of implant
g) Malalignment
h) Fracture of bone
j) Penetration of implant across joint space
k) Penetration of implant through bone
m) Fracture of implant
n) Permanent deformation of implant
p) Other

A-15. Reason(s) for removal (Indicate *Yes* or *No-mark* primary reason with an asterisk)

a) Routine
b) Early infection (<6 months)
c) Late infection (>6 months)
d) Breakage or deformation of implant
e) Pain in the vicinity of implant
f) Stiffness of joint in vicinity of implant
g) Prominence of bursae
h) Instability
j) Unsatisfactory position of implant
k) Non-union
m) Allergic or hypersensitive reaction
n) Reasons not known
p) Other (specify)

A-16. Findings at surgery (Indicate *Yes*, *No*, *Doubt*, or *Not applicable*)

a) Pus
b) Scar tissue
c) Granulation tissue
d) Foreign body (debris or stained tissue)
e) Bursal fluid
f) Implant easily removed
g) Fractured grouting agent
h) Caseation
j) Boney reaction
k) Other

A-17. Swab from implant site (Indicate *Yes* or *No*)

a) Swab from implant site
b) Sterile
c) If no, indicate type

A-18. Examination of tissue .....

APPENDIX B

(*Clauses* 6.3 *and* 6.3.1)

RECOVERY OF IMPLANTS, ENGINEERING EXAMINATION

B-1. Implant..... Type.....

B-2. Number of components .....

B-3. Macroscopic examination (Indicate *Yes, No, Doubt,* or *Not applicable*)

	Location	*Estimate Degree*
a) Wear or burnishing	—	—
b) Galling	—	—
c) Scratching	—	—
d) Change of shape	—	—
e) Mechanical damage	—	—
f) Macro porosity	—	—

B-4. Microscopical examination (Indicate location and orientation of sample)

a) Inclusion content (recommended practice)
b) Grain size
c) Grain boundary constituents
d) Microporosity
e) Other distinguishing features (for example, cast stainless steel-delta-ferrite)
   i) —
   ii) —
   iii) —

B-5. Type of material (Indicate method of determination)

a) Chemical composition

B-6. Corrosion (if *Yes*, identify)

a) General corrosion
b) Pitting corrosion
c) Crevice corrosion
d) Galvanic corrosion
e) Unable to identify

B-7. Mechanical failure (if *Yes*, identify mode)

a) Fatigue
b) Torsion
c) Impact
d) Stress-corrosion
e) Static-overstress, causing plastic deformation
f) Corrosion fatigue
g) Combination of above (identify)
h) Other (specify)
j) Unable to identify

Indicate location of failure and method of identification.

B-8. Mechanical properties (indicate *N/A* if not available). Samples should be taken from areas representative of the original material.

a) Sample size and orientation
b) Hardness (indicate type)
c) 0·2 percent offset yield stress
d) Ultimate tensile strength
e) Percent elongation
f) Reduction in area
g) Other tests as applicable (for example, transverse bend test)

B-9. Dimensions of implant

B-10. Conclusion

EXPLANATORY NOTE

In the preparation of this standard assistance has been derived from ASTM Annual Book Part 46 (F 561-78), issued by the American Society for Testing and Materials.

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